

**REMARKS****Generally**

Claims 1-3, 5, 6, 9, and 59-71 are pending in the application. In this response, claims 1, 68, and 69 have been amended for clarity and new dependent claim 75 has been added. Exemplary support for the claim amendments and new claim 75 can be found throughout the specification and claims as filed. See, for example, claim 1.

As new claim 75 contains the deleted features of claim 1 and the claims 1, 68, and 69 have been amended for clarity only, the foregoing claim amendments should be entered at this time would requiring the submission of a Request for Continued Examination.

Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections in view of the foregoing amendments and the following remarks.

**Rejections under 35 U.S.C. § 112**

(i) Claims 1-3, 5, 6, 9, and 59-71 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, it is the Examiner's position that it "is not clear how or whether the recitations of step (d) relate to or further limit step (a) - how can the method on one hand require that the probe be labeled and the molecule not be labeled...but also encompass the use of an unlabeled probe and labeled molecule". (Office Action, Page 3).

Claim 1 has been amended to delete "wherein said nucleic acid molecule is not labeled with scattered-light detectable particles". With the deletion of the foregoing, there is no lack of clarity in claim 1.

Thus, the rejection of claims 1-3, 5, 6, 9, and 59-71 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

(ii) Claims 3, 5, and 6 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, it is the Examiner's position that claims 3, 5, and 6 "require the use of an unlabeled probe and a labeled nucleic acid molecule, contradicting the requirements stated in new step (d) of claim 1". (Office Action, Page 4).

As claim 1 recites "either said nucleic acid probe or said nucleic acid molecule is labeled" and then claims 3, 5, and 6 can appropriately limit claim 1 by requiring the use of an unlabeled probe.

Thus, the rejection of claims 3, 5, and 6 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

#### **Rejections under 35 U.S.C. § 103**

(i) Claims 1-3, 5, 6, and 68-71 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 6,045,996 (hereinafter "Cronin") in view of *Yguerabide et al.*, Analytical Biochemistry, 262:137-156 (1998) (hereinafter "Yguerabide") and *Service*, Science, 282:396-399 (1998) (hereinafter "Service").

Amended independent claim 1 recites a method for detecting specifically an allele of a pharmacogenetically relevant gene involved in drug metabolism in a

sample. The method comprises, *inter alia*, contacting the sample with a capture probe (i) that is immobilized on a solid surface and (ii) that hybridizes to said nucleic acid molecule comprising said target nucleotide sequence, wherein said nucleic acid probe is labeled with scattered-light detectable particles.

The Examiner concedes that Cronin and Yguerabide "do not teach methods comprising the use of probes labeled with scatter-light detectable particles, target nucleic acids that are not so labeled, and an immobilized capture probe, wherein the capture probe is also contacted with the "allele" in the sample". (Office Action, Pages 8-9).

Service has been cited as allegedly teaching the deficiencies of Cronin and Yguerabide. In particular, Service has been cited by the Examiner as teaching "both methods in which labeled target nucleic acids are hybridized to arrays of unlabeled oligonucleotides (see page 398, left and center columns), as well as an alternative array-based method for detecting specific sequences in which unlabeled target nucleic acid is hybridized to (i.e., "captured") by array-immobilized, unlabeled oligonucleotide probes, and in which a third population of nucleic acids identified as "tagged" oligos are included in hybridization reactions to achieve determination of the sequence present in the target nucleic acid (see page 398, center column)". (Office Action, Page 9).

While Service discusses labeling DNA molecules with fluorescent tags, Service, like Cronin and Yguerabide, does not disclose or suggest contacting the sample with a capture probe. Cronin, Yguerabide, and Service fail to disclose or suggest immobilizing the probe on a solid surface and hybridizing to said nucleic acid molecule comprising said target nucleotide sequence. Cronin, Yguerabide,

and Service further fail to disclose or suggest labeling the nucleic acid probe with scattered-light detectable particles.

If the Examiner maintains his position that Service's mere disclosure of fluorescent tagged DNA molecules is somehow the same as the presently recited step (d), the Examiner's attention is directed to M.P.E.P. § 2142, which provides that the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of *the reason(s)* why the claimed invention would have been obvious. KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

The Examiner has failed to establish a *prima facie* case of obviousness of amended independent claim 1 over Cronin, Yguerabide, and Service.

In view of at least the foregoing, the obviousness rejection over Cronin, Yguerabide, and Service should be withdrawn.

(ii) Claims 9, 59-65, and 67 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Cronin in view of Yguerabide and Service, and further in view of *Yguerabide et al.*, Analytical Biochemistry, 262:157-176 (1998) (hereinafter "Yguerabide-II").

Yguerabide-II has been cited as teaching the deficiencies of Cronin and Yguerabide. In particular, Yguerabide-II has been cited to teach the features recited in claims 9, 59-65, and 67. As cited, Yguerabide-II fails to cure at least the above-noted deficiencies of the combination of Cronin and Yguerabide. Accordingly, claims 9, 59-65, and 67 are patentable over the cited references for at least the same reasons for which amended independent claim 1 is patentable.

(iii) Claims 61, 64, and 66 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Cronin in view of Yguerabide, Service, Yguerabide-II, and further in view of *Haider et al.*, Experimental Cell Research, 234:498-506 (1997) (hereinafter "Haider").

Haider has been cited as teaching the deficiencies of Cronin, Yguerabide, and Yguerabide-II. In particular, Haider has been cited to teach the features recited in dependent claims 61, 64, and 66. As cited, Haider fails to cure at least the above-noted deficiencies of the combination of Cronin, Yguerabide, and Yguerabide-II. Accordingly, claims 61, 64, and 66 are patentable over the cited references for at least the same reasons for which amended independent claim 1 is patentable.

### **Conclusion**


Applicants invite the Examiner to contact Applicants' representative at the telephone number listed below if any issues remain in this matter, or if a discussion regarding any portion of the application is desired by the Examiner.

In the event that this paper is not timely filed within the currently set shortened statutory period, Applicants respectfully petition for an appropriate extension of time. The fees for such extension of time may be charged to our Deposit Account No. 02-4800.

In the event that any additional fees are due with this paper, please charge  
our Deposit Account No. 02-4800.

Respectfully submitted,

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